

## VS 800 series Memoranda and CVB Notices - Historical Summary of Proposed Documents

ID	Title	Document Type	Date Closed for Comment	Current Status	Final Disposition
518	Safety Data to Support Using Multiple Strains of Potentially Immunosuppressive Viruses in the Same Modified Live Product	CVB Notice	2/3/2014	Finalized	CVB Notice 14-06
517	Discontinuing the Use of RelPot Software	CVB Notice	11/18/2013 (extended)	Finalized	Published as CVB Notice 13-18
515	Summary of Changes for Related Study Protocols	CVB Notice	11/18/2013 (extended)	Finalized	Published as CVB Notice 13-17
511	Summary Information Format, Category IV: Production Platform for Veterinary Biologics [attachment to Draft Memo 460]	VS Memorandum attachment	7/22/2013	Finalized	Published
510	Exemptions to title 9, Code of Federal Regulations (9 CFR), part 113.28, Detection of Mycoplasma Contamination	CVB Notice	2/17/2014	Finalized	VSM 800.119
509	Changes to the Final Disposition Notification for Release of Biological Products	CVB Notice	7/22/2013	Finalized	Published as CVB Notice 13-11
508	General Licensing Considerations: Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids	VS Memorandum	11/18/2013 (extended)	Finalized	Published as VSM 800.206
506	Changes to the Rabies Virus NIH Potency Test Validity Requirements	CVB Notice	7/22/2013	Finalized	Published as CVB Notice 13-10
502	Veterinary Biological Product Samples	VS Memorandum	6/10/2013	Finalized	Published as VSM 800.59
501	Release of Biological Products	VS Memorandum	6/24/2013	Finalized	Published as VSM 800.53
496	The Use of Minimum Age Animals in Licensure Studies	VS Memorandum	4/29/2013	Active	
495	Submission of Host Animal Serum Samples for In-Vitro Potency Tests	VS Memorandum	2/25/2013	Finalized	Published as VSM 800.79
492	Change in Issuance of Permits for General Sale and Distribution	CVB Notice	12/24/2012	Finalized	Published as CVB Notice 13-03
484	Use of Polymerase Chain Reaction (PCR) Assays to Measure Potency of Inactivated Protein-Based Biologics	CVB Notice	2/4/2013	Finalized	Published as CVB Notice 13-05
480	New Policy on Biological Product Samples Submitted to the Center for Veterinary Biologics and the Confirmatory Testing Selection Period	CVB Notice	11/5/2012	Finalized	Published as CVB Notice 12-25
478	Quarterly Acknowledgement Summaries for Selected Submissions	CVB Notice	12/3/2012	Finalized	Published as CVB Notice 13-02
476	General Requirements for Test Kits Intended for the Diagnosis of Animal Diseases	VS Memorandum	3/29/2013 (extended)	Active	

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473	Conducting Dilution of Preservative Studies for Live Bacterial Vaccines	CVB Notice	10/1/2012	Finalized	Published as CVB Notice 12-21
472	Revised Procedure for Depletion of Existing Inventories of Superseded Labels	CVB Notice	7/9/2012	Finalized	Published as CVB Notice 12-14
467	Dilution of Preservative Screening for Sterility Testing of Veterinary Biologics	VS Memorandum	6/10/2013	Finalized	Published as VSM 800.120
465	Use of Humane Endpoints and Methods in Animal Testing of Biological Products	CVB Notice	4/30/12 (extended)	Finalized	Published as CVB Notice 12-12
463	Submission of Master Seeds and Master Cell Stocks to the Center for Veterinary Biologics for Confirmatory Testing	CVB Notice	1/30/2012	Finalized	Published as CVB Notice 12-08
462	Exemption from Leptospira Bacterin Testing Under 9 CFR 113.101 – 104 and the Associated References and Studies	VS Memorandum	8/5/2013	Finalized	Published as VSM 800.102
460	Guidelines for Obtaining a Conditional Veterinary Biologics License for Production Platform Derived, Recombinant, Non-replicating, Nonviable Constructs	VS Memorandum	5/20/2013	Finalized	Published as VSM 800.213
458	Exemption to Shipping a Sample of Inactivated lot or Bulk Rabies Antigen to the Center for Veterinary Biologics	CVB Notice	1/16/2012	Finalized	Published as CVB Notice 12-03
453	Animal Safety Testing Exemption	VS Memorandum	12/24/2012 (re-posted)	Finalized	Published as VS Memo 800.116
449	Virulent Systemic Feline Calicivirus Label Claims	CVB Notice	4/23/2012 (re-posted)	Finalized	Published as CVB Notice 12-11
448	Appropriate Use of Controls for CAV PCR Testing and Availability of an Extraneous Agent PCR Testing Protocol	CVB Notice	8/29/2011	Finalized	Published as CVB Notice 12-04
444	Product Licensing Plans	CVB Notice	5/2/2011	Finalized	Published as CVB Notice 11-12
443	Discontinued Reagents: Standard Reference Preparations and Test Reagents for Virus Biological Products	CVB Notice	5/9/2011	Finalized	Published as CVB Notice 11-15
440	Guidelines for Determining Release and Throughout-Dating Potency Specifications	VS Memorandum	3/31/2014	Active	
439	Guidelines for Master Reference Qualification and Requalification	VS Memorandum	4/4/2011	Finalized	Published as VS Memo 800.211
438	Testing Exemptions for Antibody Product Donor Animals	CVB Notice	11/21/2011	Finalized	Published as CVB Notice 12-05
437	Paper Reduction Initiatives	CVB Notice	4/18/2011	Finalized	Published as CVB Notice 11-10

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430	General Licensing Considerations: Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids	VS Memorandum	2/21/2011	Finalized	Published as VS Memo 800.206
426	Export of Serials Before Completion of Serial Release Testing	VS Memorandum	8/15/2011	Finalized	Published as VSM 800.83
424	U.S. Veterinary Biological Product Permits for Distribution and Sale	VS Memorandum	10/1/2012	Finalized	Published as VSM 800.101
422	The Management and Disposition of Eggs, Chickens and Biological Products Following a Chicken Anemia Virus (CAV) Outbreak in a Source Flock	CVB Notice	9/27/2010	Finalized	Published as CVB Notice 11-01
420	Use of Symbols on Labeling for Diagnostic Test Kits	CVB Notice	4/18/2011 (extended)	Finalized	Published as CVB Notice 11-14
414	Obtaining the Testing Plan for Authorized Master Seed/Master Cell Sample submission	CVB Notice	8/30/2010	Finalized	Published as CVB Notice 10-11
413	Generation and Implementation of Draft Policy	CVB Notice	8/30/2010	Finalized	Published as CVB Notice 11-02
412	Preparation of Experimental Products at Licensed Establishments	VS Memorandum	2/28/2011	Finalized	Published as VS Memo 800.64
406	Preparation and Submission of Facilities Documents	VS Memorandum	8/9/2010	Finalized	Published as VS Memo 800.78
405	Special Labels for Product for Export	VS Memorandum	9/27/2010 (extended)	Finalized	Published as VS Memo 800.208
402	Alternative Test Procedure for Tuberculin, PPD Bovis, Intradermic	VS Memorandum	3/21/2011 (extended)	Finalized	Published as VS Memo 800.114
395	Minor Temperature Deviations of Biological Products	VS Memorandum	8/16/2010	Finalized	Published as VS Memo 800.210
380	Expiration Date Extension and Discontinued Reagents: Salmonella Standard Reference Bacterins	CVB Notice	6/8/2009	Finalized	Published as CVB Notice 09-23
368	Rabies Safety Tests per 9 CFR Part 113.209	CVB Notice	7/19/2010	Finalized	CVB Notice 11-18
367	Qualification of Leptospira Canicola, Leptospira Grippotyphosa, Leptospira Icterohaemorrhagiae, and Leptospira Pomona Reference Bacterins for Products Intended for Use in Swine and/or Cattle	CVB Notice	6/8/2009	Finalized	Published as CVB Notice 09-16
363	Potency Testing by Unlicensed Facilities	VS Memorandum	4/15/2013 (reposted)	Finalized	Published as VS Memo 800.115
361	Changes to the Administrative Inspection Review Program	CVB Notice	10/6/2008	Finalized	Published as CVB Notice 08-18

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ID	Title	Document Type	Date Closed for Comment	Current Status	Final Disposition
360	Disposal of Classical Swine Fever Virus Seeds	Federal Register Notice	2/4/2009		Published for Comment in Federal Register, Vol 74, No 2, Notices
356	Appendix III - Guidance for Validating ELISA Relative Potency Assays	VS Memorandum Appendix	4/18/2011 (extended)	Finalized	Appendix to VSM 800.112
352	Conversion Formulas for SP Ratio to Titer in Diagnostic Kit Inserts	CVB Notice	12/8/2008	Finalized	Published as Notice 09-04
351	Guidelines for Live Master References	VS Memorandum	1/26/2009	Finalized	VSM 800.118
350	Bovine Coronavirus and Rotavirus Reference Qualification by Colostral Antibody Titers	VS Memorandum	11/10/2008	Finalized	Published as VS Memo 800.209
345	General Licensing Consideration: Efficacy Studies	VS Memorandum	8/25/2014	Finalized	Published as VSM 800.202
344	General Licensing Consideration: Study Practices and Documentation	CVB Notice	3/17/2014	Finalized	Published as VSM 800.200
337	Follow-up Sterility Check Testing	CVB Notice	2/12/2010	Finalized	Published as CVB Notice 10-10
336	Electronic Freedom of Information Act Involving Veterinary Biological Products	VS Memorandum	4/28/2008	Inactive	Waiting on one-tier label claim regulation
335	Guidelines for Autogenous Biologics	VS Memorandum	5/18/2009	Finalized	Published as VS Memo 800.69
334	Dilution of Preservative Screening for Plate-Based Sterility Tests	CVB Notice	6/22/2009	Finalized	Published as CVB Notice 09-25
331	General Licensing Considerations: Target Animal Safety Studies Prior to Product Licensure	VS Memorandum	9/14/2009	Finalized	Published as VS Memo 800.207
330	Reinstatement and Dating Extension for Erysipelothrix Rhusiopathiae Standard Reference Bacterin, Serial 5	CVB Notice	2/4/2008	Finalized	Published as CVB Notice 08-04
329	Guidelines for Submitting Electronic Data Files for Statistical Analysis	VS Memorandum	5/19/2008	Finalized	Published as VS Memo 800.96
328	Reporting Inactivation Test Results on APHIS Form 2008 for Inactivated Veterinary Biological Products with the Restriction "For Further Manufacture (FFM)"	CVB Notice	12/3/2012	Finalized	Published as CVB Notice 13-06
327	Studies to Support Revaccination Claims	CVB Notice	8/9/10 (extended)	Inactive	

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321	General Licensing Considerations: Backpassage Studies,	VS Memorandum	2/4/2008	Finalized	Published as VS Memo 800.201
320	Market Suspension	VS Memorandum	12/30/2011	Finalized	Published as VS Memo 800.57
315	Consistency of Avian Safety Testing Parameters in Outlines of Production for Multi-fraction Avian Products	CVB Notice	10/22/2007	Finalized	Published as CVB Notice 09-05
314	Vaccine Claims for Protection of the Fetus Against Bovine Virus Diarrhea Virus	VS Memorandum	11/15/2010	Finalized	VSM 800.212
313	Labeling of Equine Influenza and Swine Influenza Vaccines	CVB Notice	8/6/2007	Finalized	Published as CVB Notice 07-17
284	Qualification of Leptospira pomona and Leptospira canicola Reference Bacterins for Products Intended for Use in Dogs	CVB Notice	7/9/2007	Finalized	Published as CVB Notice 07-12
270	Sublicensing of Veterinary Biological Products	VS Memorandum	6/25/2007	Finalized	Published as VS Memo 800.58
269	Export Certificates and Certificates of Licensing and Inspection for Animal Biological Products	VS Memorandum	6/26/2007	Active	
268	Biological Products Returned to Licensed or Permitted Establishments	VS Memorandum	12/3/2007	Finalized	Published as VS Memo 800.60
267	Disposal of Unsatisfactory and Undesirable Materials	VS Memorandum	12/10/2007	Finalized	Published as VS Memo 800.56
166	Additives in Animal Biological Products	VS Memorandum	6/25/2007	Finalized	Published as VS Memo 800.51
155	Product Stability Studies	CVB Notice	8/2/10 (extended)	Active	
132	Guidelines for Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids	VS Memorandum	4/2/2007	Finalized	Published as VS Memo 800.206
131	Electronic Maintenance of Paper Records	CVB Notice	2/11/2008	Finalized	Published as CVB Notice 08-19
129	Post Challenge Observation Periods for Efficacy Studies	CVB Notice	3/19/2007	Finalized	Published as CVB Notice 07-07
125	General Licensing Considerations: Field Safety Studies	VS Memorandum	1/8/2007	Finalized	Published as VS Memo 800.204
121	Submission of Outsourced Studies	CVB Notice	2/26/2007	Finalized	Published as CVB Notice 07-04
116	Preparation and Testing of Experimental Biological Products that are Derived from Biotechnology	CVB Notice	4/30/2007	Finalized	Published as CVB Notice 07-06

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113	Potency Reference Preparation Summaries	VS Memorandum	3/19/2007	Finalized	Published as VS Memo 800.92
111	Guidance for Inactivation Studies	VS Memorandum	5/7/2012 (re-posted) (extended)	Finalized	Published as VSM 800.117
110	Guidelines for Validation of In Vitro Potency Assays	VS Memorandum	4/16/2007	Finalized	Published as VS Memo 800.112
109	Viral Strain Changes in Equine Influenza and Swine Influenza Vaccines (Killed Virus)	VS Memorandum	2/20/2007	Finalized	Published as VS Memo 800.111
108	General Licensing Considerations: Antigen Interference	VS Memorandum	10/23/2006	Finalized	Published as VS Memo 800.203
105	Advertising and Promotional Materials	VS Memorandum	7/2/2007	Finalized	Published as VS Memo 800.98

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